UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

DAWN TUCKER, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 4:20-CV-1543 RLW
	)	
ETHICON, INC, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on the parties' motions to exclude expert general causation opinions under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). (ECF Nos. 84-87, 89, 91, 93.)

I. Factual and Procedural Background

The Plaintiffs are a married couple who reside in Missouri. On November 15, 2011, Ms. Dawn Tucker underwent implantation of a Johnson & Johnson Gynecare TVT Secur ("TVT-S") pelvic mesh device. The TVT-S device is used to treat stress urinary incontinence. Dr. Jack Ricketts, M.D., performed the surgery in St. Louis, Missouri. The Defendants designed, manufactured, and/or sold the TVT-S. The TVT-S allegedly caused various injuries to Ms. Tucker, including vaginal pain, pelvic pain, severe pain with intercourse, recurrence of incontinence, urinary tract infections, urinary frequency and urgency, and urinary retention. (ECF No. 35-1 at 5-6.)[1] Ms. Tucker alleges that the "bodily injuries related to the mesh often brings [her] to tears and it has caused a loss of intimacy between" her and her husband, and has diminished

[1]All references to page numbers refer to the pagination automatically generated by the Court's CM/ECF electronic filing system that appears at the top of each page of an electronically filed document. These do not necessarily correspond to native page numbers on the document.

her overall quality of life because of constant pain. (Id. at 6.) Ms. Tucker subsequently underwent two surgeries to remove or revise the pelvic mesh in 2012 and 2015, both performed in Missouri.

On September 23, 2016, Plaintiffs filed suit against Defendants on a Short Form Complaint in a multidistrict ligation ("MDL"), In re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation, MDL No. 2327, in the United States District Court for the Southern District of West Virginia. The MDL relates to allegedly defective pelvic mesh products including the TVT-S. Numerous motions filed in the MDL case were pending at the time the case was transferred to this Court in October 2020. The Court granted in part and denied in part Defendants' Motion for Partial Summary Judgment on February 5, 2021 (ECF No. 82), and largely denied Defendants' motions to limit the case-specific opinions and testimony of Plaintiffs' expert witnesses Dr. Michaels and Dr. Rosenzweig on March 4, 2021 (ECF No. 95).

With the parties' agreement, the Court adopted the MDL Court's prior orders pertaining to general expert testimony. See Joint Summary of MDL Rulings on General Daubert Motions (ECF No. 78) ("Joint Summary"); Order Adopting MDL Court's Orders Regarding Experts (ECF No. 117). The MDL Court reserved ruling on a number of issues related to the parties' general causation experts. Plaintiffs filed motions to exclude the opinions of Defendants' general causation expert witnesses Dr. Brian J. Flynn, M.D., Dr. Salil Khandwala, M.D., and Dr. Christopher Ramsey, M.D. Defendants filed motions to exclude the opinions of Plaintiffs' general-causation expert witnesses Dr. Bruce Rosenzweig, M.D., Prof. Dr. Med. Uwe Klinge, Dr. Paul J. Michaels, M.D., and Dr. Ralph Zipper, M.D.

II. Legal Standards

The Eighth Circuit recently expounded on the applicable standards for admissibility of expert testimony under Federal Rule of Evidence 702 and Daubert:

> As the proponent of the expert testimony in question, Plaintiffs have the burden to prove its admissibility by a preponderance of the evidence. *Lauzon v.*

Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). Federal Rule of Evidence 702 governs the admissibility of expert testimony, and under this rule the district court is "vested with a gatekeeping function, ensuring that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Union Pac. R.R. v. Progress Rail Servs. Corp.*, 778 F.3d 704, 709 (8th Cir. 2015) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). In exercising this gatekeeping function, the district court has "broad discretion," and "on appeal we will not disturb a decision concerning the exclusion of expert testimony absent an abuse of that discretion." *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006).

That said, we have recognized that the "liberal thrust" of Rule 702 regarding the admissibility of expert testimony creates "an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review." *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014). "While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony." *Id.* (collecting authorities).

Rule 702's "screening requirement" has been "boiled down to a three-part test." *Id.* at 561. First, the testimony must be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant. *See id.* Second, the expert must be qualified to assist the finder of fact. *Id.* Third, the testimony must be reliable or trustworthy in an evidentiary sense. *Id.* At issue here is the third part of this test—whether Plaintiffs' experts' proposed testimony meets Rule 702's reliability requirement. "The standard for judging the evidentiary reliability of expert evidence is 'lower than the merits standard of correctness.'" *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).

The reliability inquiry is a "flexible" one, with "[m]any factors" bearing on it. *Daubert*, 509 U.S. at 593-94. In *Daubert*, the Court articulated "four non-exclusive factors" relevant to this inquiry. *Johnson*, 754 F.3d at 562. These factors are (1) whether the expert's theory or technique can be or has been tested, (2) whether the theory or technique has been subjected to peer review or publication, (3) the known or potential rate of error of the theory or technique, and (4) whether the technique or theory is generally accepted. *See id.*; *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996). Factors recognized since *Daubert* include "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

Additionally, while *Daubert* instructed that the focus of the reliability inquiry "must be solely on principles and methodology, not on the conclusions that they generate," 509 U.S. at 595, the Supreme Court later clarified that "conclusions and methodology are not entirely distinct from one another," *Gen. Elec. Co. v.*

> *Joiner*, 522 U.S. 136, 146 (1997). Thus, "a district court's focus on principles and methodology need not completely pretermit judicial consideration of an expert's conclusions," *Kuhn*, 686 F.3d at 625 (internal quotation marks omitted), and a district court may exclude expert testimony if it finds "that there is simply too great an analytical gap between the data and the opinion proffered," *Joiner*, 522 U.S. at 146. Or, to put it in the language we have frequently used both before and after *Daubert* and *Joiner*, a district court may exclude an expert's opinion if it is "so fundamentally unsupported" by its factual basis "that it can offer no assistance to the jury." *E.g.*, *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988); *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011).
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> When a district court excludes an expert's opinion for being fundamentally unsupported, yet another "intriguing juxtaposition" is evident in our case law. *See Johnson*, 754 F.3d at 562. On the one hand, we have recognized that we owe "significant deference" to the district court's "determination that expert testimony is excessively speculative," and we "can reverse only if we are convinced that the District Court made a clear error of judgment on the basis of the record before it." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) (internal quotation marks omitted). On the other hand, we have stated numerous times that, "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *E.g.*, *United States v. Coutentos*, 651 F.3d 809, 820 (8th Cir. 2011); *see also Klingenberg v. Vulcan Ladder USA, LLC*, 936 F.3d 824, 829-30 (8th Cir. 2019) (distinguishing cases where we affirmed the exclusion of experts' opinions as too speculative because, in those cases, the experts' opinions were "wholly speculative," "connected to the facts by only the expert's *ipse dixit*," "patent speculation," "pure conjecture," and "vague theorizing based upon general principles").
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> Thus, excluding an expert's opinion for being fundamentally unsupported is an exception to the general rule that "[g]aps in an expert witness's . . . knowledge" go to weight, not admissibility. *See Robinson v. GEICO Gen. Ins.*, 447 F.3d 1096, 1100 (8th Cir. 2006); *cf. Finch*, 630 F.3d at 1062 ("Doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility." (brackets omitted)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" of addressing "shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

In re Bair Hugger Forced Air Warming Devices Prod. Liab. Litig. (Amador v. 3M Co.), No. 19-2899, 2021 WL 3612753, at *4-5, __ F.4th __ (8th Cir. Aug. 16, 2021) ("Amador") (reversing district court's exclusion of plaintiffs' general-causation medical experts' opinions in products liability multidistrict litigation). With these standards in mind, the Court turns to the parties' motions.

III. Plaintiffs' Daubert Motions as to General Causation Expert Opinions

A. Dr. Brian J. Flynn, M.D.

Plaintiffs do not challenge the relevance of Dr. Flynn's general causation opinions or his qualifications. As in Amador, Plaintiffs challenge only the reliability of Dr. Flynn's opinions. The parties' Joint Summary identifies two outstanding issues on which the MDL Court reserved ruling: (1) whether Dr. Flynn's opinions regarding laser-cut and mechanical-cut mesh are reliable; and (2) whether Dr. Flynn's opinions regarding safety and efficacy are reliable.

Dr. Flynn is a board-certified practicing urologist in Colorado and a Professor of Surgery and Co-Director of Female and Reconstructive Urology/Urodynamics at the University of Colorado School of Medicine. He is subspecialty certified in Female Pelvic Medicine and Reconstructive Surgery with extensive experience in the treatment of stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"), as well as removal of approximately 50 vaginal mesh and sling systems each year. Dr. Flynn is offered as a defense expert witness and has submitted a lengthy expert report regarding the TVT-S product used to treat Ms. Tucker.

1. Laser-Cut versus Mechanical-Cut Mesh Opinion

Dr. Flynn's general causation expert report states that he has "used both mechanical-cut and laser-cut mesh, and clinically there is no difference between the two." (ECF No. 84-1 at 17-18.) Plaintiffs move to exclude this testimony, asserting there is no reliable basis for it.

As a threshold matter, Defendants respond that while Dr. Flynn is qualified to offer opinions about the cutting of mesh, such opinions are not relevant in this case because they do not fit the facts of the case. Specifically, Defendants state that Plaintiffs' expert Dr. Rosenzweig does not opine in his case-specific report that Ms. Tucker sustained any injuries because the mesh used in her TVT-S product was cut with a laser, or identify a TVT-S with mechanically cut mesh as a safer design. Plaintiffs do not respond to this assertion in their Reply. The Court will address

Plaintiffs' arguments, though it is possible the testimony they challenge may turn out to be neither relevant nor offered at trial. See Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1056 (8th Cir. 2000) ("Even a theory that might meet certain Daubert factors, such as peer review and publication, testing, known or potential error rate, and general acceptance, should not be admitted if it does not apply to the specific facts of the case.") (citations and footnote omitted).

Plaintiffs' first argument is that Dr. Flynn admitted in a deposition he was not an expert with regard to the topic of laser-cut versus mechanically cut mesh, but now purports to be such an expert. Plaintiffs' argument takes the statement out of context. Dr. Flynn was asked whether he had read what internal Ethicon employees, scientists, and medical directors were saying about the issues concerning the two types of mesh. (ECF No. 84-4 at 4, Flynn 1/7/15 Dep. 64:7-24.) Dr. Flynn answered that he was not an Ethicon employee and did not develop the mesh, and his role in the case was not to discuss the biomechanical data as to differences between the two meshes because "other people that are experts for Ethicon . . . can probably speak to it better" than he could. But he testified he is qualified "to answer questions as a physician and clinician with respect to laser-cut and mechanically-cut [mesh]." (Id. 65:1-25.) Thus, Dr. Flynn did not admit he lacks expertise to opine on clinical differences between the kinds of mesh. Further, the Court notes the MDL court rejected the related argument that Dr. Flynn was not qualified to opine on mesh degradation, pathology, and design. See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2327, 2016 WL 4556807, at *4 (S.D. W. Va. Aug. 31, 2016) ("Dr. Flynn is a board-certified urologist, with undergraduate training in biomedical engineering" and his "extensive clinical experience, combined with [his] review of scientific literature, qualifies [him] to opine on mesh's reaction to and effect on the human body").

Plaintiffs next argue the opinion should be excluded because Dr. Flynn was unable to identify specific papers in the scientific literature that distinguish between the types of mesh, and

could not identify which mesh was used in any specific study. Plaintiffs also argue that Dr. Flynn's testimony he did not observe any substantial difference in outcomes between laser and mechanically cut mesh in his clinical experience is unreliable because he had to guess how many Ethicon products he has implanted, he does not know how many of the TVT devices he implanted were laser cut, he does not keep track of the products involved in revision surgeries, and he has not reviewed his patient files.

In a deposition, Dr. Flynn was asked how he has confidence in his opinion that laser-cut and mechanically cut mesh are both safe and effective, given that no literature has made a head-to-head comparison of the performance of the two meshes. He responded:

> Well, I've implanted over 800 midurethral slings. And I've been using midurethral slings since 2004. So I've used both mechanical-cut and laser-cut mesh. That's what was taught to me as a resident and fellow and what I incorporated in my practice. So from my own clinical experience from 2004 to 2006, maybe even later, 2008, when using mechanical-cut mesh, I got excellent results. I had over 90 percent success with a complication rate of somewhere around 2 to 2 and a half percent.
>
> Later in my practice I switched over to laser-cut mesh [including] the . . . TVT-Secur. [A]ll of these products performed quite similarly in terms of having efficacy and safety that was very similar to the mechanical-cut.
>
> So after doing 800 cases, I'm very comfortable commenting on both of the meshes. I found the way they resulted in my patients and the outcomes I got were quite similar.

(ECF No. 96-2 at 5, Flynn 4/19/16 Dep. 127:24-128:20.)

Other district courts addressing this issue have concluded that Dr. Flynn's opinion as to the two kinds of mesh is sufficiently reliable for purposes of Rule 702 based on his extensive clinical experience and review of relevant medical literature. See McBroom v. Ethicon, Inc., No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *7 (D. Ariz. July 1, 2021) ("Dr. Flynn's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of Rule 702."); Heinrich v. Ethicon, Inc., No. 2:20-cv-00166-APG-VCF, 2021 WL 1854648, at *3 (D. Nev. May 10, 2021) ("Flynn has explained the bases of his opinion,

and it is grounded in the medical literature and his own experience. The fact that he is not a materials scientist does not preclude him from opining on whether the two cuts have clinically significant differences."). This Court agrees with these conclusions.

Further, "A medical expert need not be able to testify 'as to exact statistics about his patients . . . to opine as to the large-scale safety and efficacy' of a medical device. Winebarger v. Bos. Sci. Corp., No. 2:13-CV-28892, 2015 WL 1887222, at *34 (S.D. W. Va. Apr. 24, 2015) (emphasis omitted)." Heinrich, 2021 WL 1854648, at *2. "Rather, such an opinion may be sufficiently reliable if it is based on the expert's observations in his own clinical practice that is 'on par with the findings' in medical literature the expert cites. Tyree v. Bos. Sci. Corp., 54 F.Supp.3d 501, 585 (S.D. W. Va. 2014), as amended (Oct. 29, 2014) (quotation omitted)." Id.

Plaintiffs' various arguments go to the credibility and weight of Dr. Flynn's testimony and as such are appropriate for cross-examination, rebuttal expert testimony, and argument to the jury, but they do not provide a basis under Rule 702 to exclude Dr. Flynn's opinions as to laser-cut and mechanically cut mesh.

2. Safety and Efficacy Opinions

Dr. Flynn's general causation expert report includes various opinions on the safety and efficacy of the TVT-S product that was implanted in Ms. Tucker.

Plaintiffs state that the MDL Court characterized Dr. Flynn's review of the medical literature as "shaky" and "based on a crumbling foundation," and assert that the MDL Court "clearly ruled that the medical and scientific literature does not constitute a reliable foundation for Dr. Ramsey's [sic] experience[.]" (ECF No. 84 at 8-9.) In a one-page discussion, Judge Goodwin described Dr. Flynn's general safety and efficacy opinions as "shaky" to the extent they are based on medical literature, because he "focused only on medical literature that supported his opinion, ignoring relevant, contrary medical literature while not explaining his reason for doing so." In re

Ethicon , 2016 WL 4556807, at *3. But the MDL court did not exclude Dr. Flynn's safety and efficacy opinions on that basis, contrary to Plaintiffs' assertion that this was a settled issue, and applicable Eighth Circuit standards do not support their exclusion.

The gist of Judge Goodwin's criticism was that Dr. Flynn cherry-picked the medical literature. In this context, the Eighth Circuit has explained that "it is not the province of the court to choose between competing theories when both are supported by reliable scientific evidence." Kuhn v. Wyeth, Inc., 686 F.3d 618, 633 (8th Cir. 2012); see also In re Nuvaring Prod. Liab. Litig., No. 4:08-MD-1964 RWS, 2013 WL 791835, at *4 (E.D. Mo. Mar. 4, 2013) ("As to cherry picking data, the Eighth Circuit has recently made clear that such allegations should be left for cross-examination."). "'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means' of addressing 'shaky but admissible evidence.' Daubert, 509 U.S. at 596." Amador, 2021 WL 3612753, at *5.

In addition, the Defendants assert that the MDL Court's ruling was made in the context of Dr. Flynn's expert reports concerning five different devices, and in challenging his opinions the MDL Plaintiffs focused on his testimony about another device not at issue in this case, not the TVT-S. In the Wave 1 briefing that was before the MDL Court, the plaintiffs identified only a single scientific publication related to TVT-S that Dr. Flynn did not consider, a Cochrane review by Nambiar, et al., titled "Single Incision Sling Operations for Urinary Incontinence in Women." (ECF No. 96-5 at 5-6.) Defendants state that subsequently, Dr. Flynn testified he had reviewed the article and has answered questions about it,[2] included the article on his reliance list, and

[2]Defendants' discussion of Dr. Flynn's testimony includes quoted material from portions of his deposition taken March 24, 2016 (ECF No. 96 at 7-8). The Court has carefully reviewed the pinpoint deposition cites (ECF No. 96-7) and does not see the quoted information. The Court conjectures that Defendants may have cited to the wrong Flynn deposition, and notes that Plaintiffs did not challenge the quoted testimony or deposition citations.

prepared a November 15, 2018 TVT-S report addendum that addresses the Cochrane review in some detail (ECF No. 96-8).

The Court finds Dr. Flynn's safety and efficacy opinions are sufficiently reliable to be admitted under Rule 702. Plaintiffs' motion to exclude Dr. Flynn's general causation opinions will be denied in all respects.

B. Dr. Salil Khandwala, M.D.

Plaintiffs challenge the reliability of Dr. Khandwala's general causation opinions. The parties' Joint Summary identifies two outstanding issues on which the MDL Court reserved ruling: (1) whether Dr. Khandwala's opinions on mesh contraction are reliable; and (2) whether Dr. Khandwala's opinions on mesh porosity and stiffness are reliable. (ECF No. 78 at 28.) The parties' Joint Summary also states inconsistently, however, that the MDL Court "den[ied] Plaintiff's challenge to Khandwala's qualifications regarding mesh porosity and stiffness." (Id. at 20, citing ECF No. 60-14 at 6-7, MDL Dkt. No. 2778.)

Dr. Khandwala is board certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. Dr. Khandwala has used polypropylene mesh in more than 1,000 SUI procedures and over 800 POP procedures, designed and participated in clinical trials related to pelvic reconstructive surgery and pelvic mesh, spoken and published in the fields of urinary incontinence and pelvic organ prolapse, and has broad experience teaching in these fields. In addition to his clinical and scholarly experience, Dr. Khandwala relied on an extensive review of the medical literature and other information in preparing his opinions. (ECF No. 98-3, Dr. Khandwala's Reliance Materials List.)

1. Opinions on Mesh Contraction

Plaintiffs contend that Dr. Khandwala's opinions on mesh contraction—which they describe as "one solitary sentence of his report that polypropylene mesh does not contract"—are

unreliable and must be excluded. (See ECF No. 85 at 4.)[3] Plaintiffs first challenge the medical literature on which Dr. Khandwala relies for his opinion. The MDL Court found, however, "As to contraction, Dr. Khandwala's opinion is supported by 'extensive clinical experience and his analysis of the scientific literature.'" (ECF No. 60-14 at 7.) The Court will not reexamine this finding.

Plaintiffs next argue Dr. Khandwala's opinion as to mesh contraction is not reliable because while he implants and occasionally removes mesh in his clinical practice, he has not conducted any testing of explanted mesh to analyze for shrinking or contraction, and draws his conclusion based upon "gross observations" and without evidence. Dr. Khandwala is not a pathologist, but pathological studies are not required to form a reliable opinion. He explained his reliance on numerous scientific resources in arriving at his opinion and further explained his observations in clinical experience. (ECF No. 98-1 at 75-80; 115-119; ECF No. 98-3.) Dr. Khandwala's education, training, specialized knowledge, and the fact that his opinions are based on his extensive clinical experience and review of the scientific evidence and medical literature, render the opinions sufficiently reliable for admission. See McBroom, 2021 WL 27009292, at *10-11 (finding Dr. Khandwala's opinions on mesh contraction reliable and admissible); Mason v. Ethicon, Inc., No. 6:20-CV-1078-RBD-DCI, 2021 WL 2580165, at *2 (M.D. Fla. June 10, 2021) ("Dr. Khandwala's extensive experience with vaginal mesh augmentation procedures and reliance on numerous studies, is a sufficiently reliable basis to opine on mesh contraction.").

A number of courts have admitted expert opinions in comparable circumstances. See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2016 WL 4599218, at *3 (S.D.W. Va. Sept. 2,

[3]Plaintiffs' characterization of Dr. Khandwala's expert report fails to recognize that he discusses contraction for several pages, and mentions three studies as support for his opinion that TVT-S mesh does not contract or shrink. (ECF No. 98-1 at 79-81; Khandwala Expert Report at 76-78.)

2016) (Dr. Khandwala's "extensive clinical experience qualifies [him] to opine on mesh's reaction to and effect on the human body from a clinical perspective"); Trevino v. Bos. Sci. Corp., No. 2:13-CV-01617, 2016 WL 2939521, at *44 (S.D. W. Va. May 19, 2016) ("[Dr. Douso] has extensive experience with BSC's products for treating SUI and POP, including use of the . . . mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice.") (internal citations omitted); Winebarger, 2015 WL 1887222, at *26 ("[A] urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body.") (citation omitted); In re Bard IVC Filters Prod. Liab. Litig., No. MDL 15-02641-PHX DGC, 2017 WL 6554163, at *4 (D. Ariz. Dec. 22, 2017) ("The Court finds that the doctors' knowledge and experience in the field of interventional radiology and the use of IVC filters in patients form a sufficient foundation for their opinions."). The Court will not exclude Dr. Khandwala's opinions on mesh contraction.

2. Opinions on Mesh Porosity and Stiffness

The MDL Court denied Plaintiffs' challenge to "Dr. Khandwala's qualifications regarding mesh porosity and stiffness," (ECF No. 78 at 20, citing ECF No. 60-14 at 6-7, MDL Dkt. No. 2778), but reserved ruling on the reliability of his opinions on porosity and stiffness. (ECF No. 60-14 at 7; stating the MDL Plaintiffs' grounds for excluding Dr. Khandwala's testimony on mesh porosity and stiffness were "unclear").

Plaintiffs do not identify Dr. Khandwala's opinions on the porosity and stiffness of Ethicon's mesh. Plaintiffs assert in a conclusory fashion that the opinions are unreliable because

they are based on Dr. Khandwala's experience as an implanting surgeon, and rely on limited and insufficient data and observation of the mesh with the naked eye. Plaintiffs do not identify any relevant data or literature Dr. Khandwala overlooked. As with his opinions on mesh contraction, the Court finds Dr. Khandwala's education, training, specialized knowledge, and the fact that his opinions are based on his extensive clinical experience and review of the scientific evidence and medical literature, render his opinions on porosity and stiffness sufficiently reliable for admission.

Plaintiffs' arguments are appropriate for cross-examination, rebuttal expert testimony, and argument to the jury, but they do not provide a basis under Rule 702 to exclude Dr. Khandwala's opinions. Plaintiffs' motion to exclude Dr. Khandwala's general causation opinions will be denied.

C. Dr. Christopher Ramsey, M.D.

Plaintiffs challenge the reliability of Dr. Ramsey's general causation opinions. The parties' Joint Summary identifies one issue on which the MDL Court reserved ruling: whether Dr. Ramsey's opinions on safety and efficacy are reliable. Dr. Ramsey is a board-certified urologist and a fellow of the American College of Surgeons who has performed over 1,000 surgeries using TVT products to treat SUI, including approximately 400 using the TVT-S product. His experience includes "long-term follow up on [his] own patients who have undergone various types of SUI surgery." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4582227, at *3 (S.D. W. Va. Sept. 1, 2016) (quoting Expert Report of C.E. Ramsey, M.D. at 1-2).

Plaintiffs do not identify Dr. Ramsey's safety and efficacy opinions. Defendants state that the gravamen of Dr. Ramsey's opinions about the safety and efficacy of the TVT-S is:

> Based on my extensive experience successfully implanting hundreds of TVT Secur slings, my discussion and collaboration with colleagues, my involvement in Professional Education events and my ongoing review of the medical literature, I can attest to the fact that TVT Secur is safely designed and effective in treating SUI.

(Ramsey Report at 10.)

On the issue of reliability, Plaintiffs state that the MDL Court characterized Dr. Ramsey's safety and efficacy opinion as "shaky" and based on a "crumbling foundation of medical literature." (ECF No. 86 at 4.) Plaintiffs assert the MDL Court "has ruled that the medical and scientific literature does not constitute a reliable foundation for Dr. Ramsey's experience, [and therefore] the only arguable basis for his opinion is his personal experience." (Id. at 5.) In a one-page discussion, Judge Goodwin found Dr. Ramsey was "qualified to offer expert testimony about the safety and efficacy of the relevant products because he has extensive experience with mesh products," but reserved ruling as to reliability of his safety and efficacy opinions, in part because Dr. Ramsey "focused mostly on medical literature provided by Ethicon, and he ignored articles contrary to or calling into question his opinion." (ECF No. 60-10 at 6.)

The Court disagrees with Plaintiffs' assertion that the MDL Court settled the issue whether Dr. Ramsey's literature review can be considered as a basis to support his safety and efficacy opinions. Judge Goodwin's criticism of Dr. Ramsey, similar to his criticism of Dr. Flynn, is that he cherry-picked the medical literature. But "it is not the province of the court to choose between competing theories when both are supported by reliable scientific evidence." Kuhn, 686 F.3d at 633; In re Nuvaring Prod. Liab. Litig., 2013 WL 791835, at *4. "'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means' of addressing 'shaky but admissible evidence.' Daubert, 509 U.S. at 596." Amador, 2021 WL 3612753, at *5.

With respect to Dr. Ramsey's experience as a basis for the reliability of his opinions, Plaintiffs argue he is a urologist with a practice devoted 70% to males, and assert he shows "an alarming lack of knowledge about information challenging the safety of the TVT-S," "does not approach issues from a scientific perspective," and his report "treat[s] unproven hypotheses as conclusions." (ECF No. 86 at 5.) Plaintiffs state Dr. Ramsey demonstrates limited knowledge of

safety concerns about TVT products, identifies the TVT-S as his product of choice although it has been removed from the market, and discounts published evidence that contradicts his personal experience.

Although the majority of Dr. Ramsey's practice concerns male patients, he routinely treats SUI issues, has performed over 1,000 mesh procedures in addition to others types of surgeries for the correction of SUI (including native tissue repairs, cadaveric and porcine fascial slings or grafts), and has performed approximately 20 mesh-removal surgeries. Dr. Ramsey has extensive clinical experience with treating SUI and with the TVT-S in particular, and his opinions are not fundamentally unsupported. The MDL Court found, in rejecting a similar argument, that Dr. Ramsey "is amply qualified to discuss the issues in this case." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2017 WL 132165, at *2 (S.D. W. Va. Jan. 12, 2017). Under the applicable Eighth Circuit standards for admission of expert opinion testimony on general causation, Plaintiffs' various challenges to Dr. Ramsey's safety and efficacy opinions go to its weight, not admissibility. The issues they raise are appropriate for cross-examination, rebuttal expert testimony, and argument to the jury, but do not provide a basis under Rule 702 to exclude the opinions.

Plaintiffs' motion to exclude Dr. Ramsey's general causation opinions as to safety and efficacy will be denied.

IV. Defendants' Daubert Motions as to General Causation Expert Opinions

A. Dr. Bruce Rosenzweig, M.D.

Dr. Bruce Rosenzweig, M.D. is a board-certified gynecologist specializing in urogynecology, a pelvic-floor surgeon, and an assistant professor of obstetrics and gynecology in Chicago, Illinois. Dr. Rosenzweig has performed over 1,000 pelvic floor surgical procedures on women with SUI and POP and over 300 surgeries to address complications related to synthetic

mesh devices. He has published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse. Dr. Rosenzweig was disclosed by Plaintiffs on issues of general and specific causation.

Defendants move to exclude certain of Dr. Rosenzweig's general causation opinions as beyond his expertise, irrelevant, unreliable, or prejudicial. Specifically, Defendants move to preclude Dr. Rosenzweig from (1) testifying that non-synthetic mesh procedures are a safer alternative; (2) criticizing the manner by which the mesh in the TVT-S was cut; and (3) testifying about duties allegedly owed by a manufacturer with respect to (i) adverse event reporting, and (ii) physician training.

1. Opinions that non-synthetic mesh procedures are safer alternatives

Dr. Rosenzweig intends to opine that the Burch procedure (a traditional surgical procedure that does not entail implanting a medical device), autologous slings (using the patient's own body tissues), and allograft slings (using donor tissue) lead to fewer complications than TVT-S for the surgical treatment of SUI. Defendants move to exclude these opinions as irrelevant to Plaintiffs' design defect claims because these alternative approaches are not medical devices, are not alternative designs of synthetic polypropylene mesh medical devices, and do not entail altering the design of the TVT-S.

The Court will deny this aspect of Defendants' Motion. The parties agree that under Missouri law, proof of an alternative design is not required as part of Plaintiffs' prima facie case for design defect. See Smith v. Brown & Williamson Tobacco Corp., 275 S.W.3d 748, 794 (Mo. Ct. App. 2008). "Missouri . . . imposes design defect liability if the plaintiff establishes 'the product, as designed, is unreasonably dangerous and therefore "defective", and that the demonstrated defect caused [her] injuries.' Nesselrode v. Exec. Beechcraft, Inc., 707 S.W.2d 371,

375-76 (Mo. 1986) (en banc) (noting Missouri has adopted Restatement § 402A)." Brinkley v. Pfizer, Inc., 772 F.3d 1133, 1140 (8th Cir. 2014).

"Yet 'Missouri courts have consistently refused to impose any "judicial definition [of unreasonably dangerous] whether derived from consumer expectations, risk-utility, or otherwise."' Id. (quoted cases omitted). "Instead, in Missouri, 'the concept of unreasonable danger . . . is presented to the jury as an ultimate issue without further definition.' Nesselrode, 707 S.W.2d at 378. 'The jury gives this concept content by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties.' Id." Brinkley, 772 F.3d at 1140. 'The parties are "entitled to assist the jury in defining the term unreasonably dangerous by presenting evidence that the utility of a design outweighs its risks, or that consumer expectations were violated, or any other theory of unreasonable dangerousness supported by the evidence."' Id. (quoted cases omitted).

Under Missouri law, testimony concerning the availability of safer and more effective alternative procedures for treatment of SUI is relevant to Plaintiffs' claims, which are not limited to design defect but also include failure to warn, negligence, recklessness, negligent and fraudulent misrepresentation, and violation of the Missouri Merchandising Practices Act. "[W]hether a safer alternative exists and whether it would have reduced or eliminated the risk of injury goes to the heart of causation and damages." Dorgan v. Ethicon, Inc., No. 4:20-00529-CV-RK, 2020 WL 5367062, at *3 (W.D. Mo. Sept. 8, 2020) (applying Missouri law; finding Dr. Rosenzweig's case-specific opinions about safer alternatives admissible). Such evidence would also be relevant to demonstrate the TVT-S's inherent risks, assist the jury in determining whether the risks of the TVT-S outweigh its benefits, and rebut any evidence that the TVT-S and similar mesh products are the best method (i.e., the "gold standard") for treating SUI. The Court will not exclude Dr. Rosenzweig's testimony as to alternative procedures.

2. Opinions on laser-cut versus mechanically cut mesh

Defendants move to exclude Dr. Rosenzweig's opinions critical of laser-cut mesh on the grounds that (1) he criticizes both kinds of mesh, (2) mechanically cut TVT-S mesh was not an available option at the time of Ms. Tucker's implant and Dr. Rosenzweig admitted it was impossible for mechanically cut mesh to be placed in a TVT-S product; (3) the opinions are irrelevant as no expert in the case has opined that Ms. Tucker sustained any injury as a consequence of the way the mesh was cut; and (4) the opinions are unreliable because Dr. Rosenzweig has not cited a single study in support of his opinion that mechanically cut mesh is safer than laser-cut mesh.

In his general expert report, Dr. Rosenzweig notes complications with both mechanical and laser-cut meshes, specifically, that mechanically cut mesh frays, has particle loss, and deforms, and that laser-cut mesh is stiff and rigid. In one deposition, Dr. Rosenzweig testified that a laser-cut mesh and a mechanically cut mesh can cause the same complications through different mechanisms. (ECF No. 88-7, Rosenzweig 2/4/16 Dep. 245:20-24.) That Dr. Rosenzweig finds issues with both methods of cutting mesh does not make his opinions fatally inconsistent or unreliable. See McBroom, 2021 WL 2709898, at *19 (citing cases); Geery v. Ethicon, Inc., No. 6:20-CV-1975-RBD-LRH, 2021 WL 2580144, at *4 (M.D. Fla. Apr. 9, 2021) (citing cases). To the extent Defendants believe that Dr. Rosenzweig's opinions in other cases may have been contradictory, this is a matter for cross-examination. McBroom, 2021 WL 2709898, at *19; Ellerbee v. Ethicon, Inc., 2021 WL 20110640, at *3 (M.D. Fla. May 20, 2021).

Plaintiffs state that mechanically cut mesh was available and used by Ethicon in other mid-urethral slings when the TVT-S was produced, but it chose to use only laser-cut mesh for the TVT-S. Plaintiffs assert that the safety of the laser-cut mesh used in the TVT-S implanted in Ms. Tucker is relevant regardless of its safety relative to mechanically cut mesh, as Ethicon internal documents

noted the laser-cut mesh "was about three times stiffer than the machine-cut TVT mesh," and Dr. Rosenzweig opines that using laser-cut mesh for the TVT-S worked in combination with its short length to make the product unreasonably dangerous. (ECF No. 101-3, Rosenzweig Report at 4-5, 14-15, 77-78.) The Court finds Defendants' second and third arguments are not a basis to exclude Dr. Rosenzweig's opinions.

Finally, Dr. Rosenzweig does not need to cite a study that mechanically cut mesh is safer that laser-cut mesh, because he does not offer such an opinion.[4] Dr. Rosenzweig's opinions about the methods of cutting mesh are based on his experience. Rosenzweig Report at 15 ("Based on my experience, training, review of the literature, and review of Ethicon's internal documents, the laser cut mesh in the TVT Exact is defective because it is too stiff and rigid."). Dr. Rosenzweig's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of Rule 702. See Geery, 2021 WL 2580144, at *4; Laderbush v. Ethicon, Inc., No. 20-cv-62-JD, 2020 WL 3000981, at *2 (D.N.H. June 4, 2020). The Court will not exclude Dr. Rosenzweig's opinions about laser-cut mesh.

3. Adverse event reporting

Defendants state that the MDL Court's Wave 1 ruling excluded Dr. Rosenzweig's "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations[.]" In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2016 WL 8788207, at *6 (S.D.W. Va. Aug. 26, 2016). Defendants ask the Court to "confirm this ruling to encompass all of Dr. Rosenzweig's adverse event reporting opinions, regardless of whether they

[4]See Defendants' Response in Opposition to Plaintiffs' Motion to Exclude or Limit the Opinions and Testimony of Brian Flynn, M.D. (ECF No. 96 at 3) ("Significantly, Dr. Rosenzweig (who is also Plaintiffs' case-specific expert) does not opine in his case-specific report that Plaintiff Dawn Tucker sustained any injuries because the mesh was cut with a laser. Doc. 88-9, Rosenzweig Case-Specific Rpt. Even if he did, his report does not identify a TVT Secur with a mesh cut differently as a safer alternative design. See id.")

are specific to compliance with FDA regulations." (ECF No. 88 at 10.) Plaintiffs respond that Defendants have not identified any specific opinions in Dr. Rosenzweig's report about adverse event reporting that they believe were left unaddressed by the MDL Court and, as a result, Plaintiffs are not "in a position to respond with regard to Dr. Rosenzweig's expertise or methods in arriving at any opinions at issue." (ECF No. 101 at 12-13.) Defendants reply that they are "simply asking to preclude [Dr. Rosenzweig] from suggesting to the jury that 'Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate and misleading' or that Ethicon deviated from the standard of care applicable to a medical device manufacturer as it relates to handling adverse event reports." (ECF No. 112 at 5, quoting Rosenzweig Report, ECF No. 101-3 at 69.)

In its Wave 1 ruling, the MDL Court stated it had "repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs . . . . [because] the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403." In re Ethicon, 2016 WL 8788207, at *6. "Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors 'to erroneously conclude that regulatory compliance proved safety.'" Id. (quoted case omitted). With respect to Dr. Rosenzweig's opinions, the MDL Court held:

> Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is EXCLUDED. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are EXCLUDED. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is GRANTED.

Id. at *6.

This Court adopted the MDL Court's ruling on Dr. Rosenzweig's opinions as to Ethicon's compliance with or violation of the FDA's adverse event reporting regulations. (ECF No. 117 at 2.) But it will deny this aspect of Defendants' motion without prejudice, as Defendants fail to identify the specific opinions they seek to exclude and offer no supporting legal arguments or citations. As a result, the Court does not know if the challenged opinions fall within the scope of the MDL Court's express ruling or, if not, whether the MDL Court's reasoning applies to the opinions. If Dr. Rosenzweig references any particular adverse event reports to support other opinions, Defendants may object as appropriate at trial.

4. Physician training

Defendants seek to exclude Dr. Rosenzweig's opinions that Ethicon did not properly train physicians regarding the use of TVT-S. Defendants contend that Dr. Rosenzweig is not qualified to testify about what level of training a medical device manufacturer should provide, and that his opinions are based on a narrative summary of documents rather than any special expertise. Defendants also contend that Dr. Rosenzweig's opinions as to physician training are irrelevant and prejudicial as neither he nor any other expert claims that Ms. Tucker's implanting surgeon was not competent or appropriately trained. Defendants assert that any of Dr. Rosenzweig's opinions about training should be limited to a discussion of "the risks of implanting mesh and whether Defendants' product materials raise those risks, but he may not offer testimony about 'what information should or should not be included in an [Instructions for Use]' or other similar materials." (ECF No. 88 at 11, quoting Walker v. Ethicon, Inc., No. 12-CV-1801, 2017 WL 2992301, at *6 (N.D. Ill. June 22, 2017).[5]

[5]The Walker case Defendants cite concerned a different expert, Dr. Shull. The MDL Court ruled that Dr. Shull could not testify about what information should be included in an IFU. In contrast, the MDL Court denied the Defendants' challenge to Dr. Rosenzweig's opinion that the TVT-S IFU should have included certain warnings. (ECF No. 60-1 at 7-8.)

Plaintiffs respond that while the MDL Court did not address whether Dr. Rosenzweig was qualified to testify that Ethicon provided inadequate training to physicians on the use of the TVT-S, it considered this argument with respect to other pelvic mesh products and determined it was an issue best reserved for trial. Plaintiffs assert that Dr. Rosenzweig has performed thousands of surgeries and many involved medical devices which he was trained to use by the manufacturer. Plaintiffs contend that as a skilled surgeon who has undergone training by device manufacturers, Dr. Rosenzweig has the necessary expertise to opine as to whether the surgeon training on implantation of the TVT-S was adequate to achieve competence in using the device. Plaintiffs assert that the TVT-S

> has unique issues when it comes to physician training which further makes Dr. Rosenzweig's opinions regarding physician training admissible. Ethicon prepared what it called a "Cookbook" after launching the TVT-Secur with additional "tips and tricks" to help physicians implant the TVT-Secur. However, Ethicon failed to include the information from the "Cookbook" in its instructions for use and chose to only provide the information to certain physicians. Plaintiff's implanting surgeon, Dr. Jack Ricketts, was never provided the "Cookbook" by Ethicon.

(ECF No. 101 at 14.)

Defendants reply that the opinions concerning physician training are irrelevant and prejudicial, and that Plaintiffs do not deny Dr. Rosenzweig opined in his case-specific report that Ms. Tucker's implanting physician's "care and treatment of Ms. Tucker met the standard of care." (ECF No. 112 at 6.)

The MDL Court has excluded proposed opinions regarding physician training and competency, concluding these opinions were irrelevant. See Wise v. C.R. Bard Inc., No. 2:12-cv-1378, 2015 WL 521202, at *13 (S.D. W. Va. Feb. 7, 2015) (citing Sanchez v. Boston Scientific Corp., No. 2:12-cv-5762, 2014 WL 4851989, at *32 (S.D. W. Va. Sept. 29, 2014)). A number of district courts have found no reason to depart from this reasoning and have excluded Dr. Rosenzweig's opinions as to physician training. See Heinrich v. Ethicon, Inc., No.

220CV00166APGVCF, 2021 WL 2290996, at *4 (D. Nev. June 4, 2021) ("Dr. Rosenzweig may not opine that Dr. Hsieh was inadequately trained because Heinrich has not shown that anyone will opine that Dr. Hsieh was inadequately trained or that he improperly implanted the TVT-S. Consequently, whether the defendants failed to train Dr. Hsieh is irrelevant to the issues in this case because there is no evidence that any failure to train led to Heinrich's injuries."); Ellerbee, 2021 WL 2010641, at *3 (excluding the opinions as irrelevant); Geery, 2021 WL 2580144, at *4 ("absent some showing that Ethicon's training is relevant to this case, the Court precludes Dr. Rosenzweig's opinion on physician training."). The MDL Court also excluded an earlier opinion of Dr. Rosenzweig's that Ethicon failed to provide adequate training to physicians regarding the use of the separate TVT-O product, describing it as a narrative review of corporate documents which was not helpful to the jury, and unreliable because Dr. Rosenzweig failed to describe the basis for his opinion that Ethicon's training was inadequate. Edwards v. Ethicon, Inc., No. 2:12-CV-09972, 2014 WL 3361923, at *10 (S.D. W. Va. July 8, 2014).

The Court finds that Dr. Rosenzweig is qualified to render opinions about physician training because he testified to his qualifications and the basis of his conclusion that Ethicon provided inadequate training, and he has trained other physicians in surgical techniques. That said, Plaintiffs have not articulated a single issue or claim that such testimony may be relevant to in this case. In the absence of a showing that Ethicon's physician training is relevant to the facts of this case, the Court will exclude Dr. Rosenzweig's training opinions. See Daubert, 509 U.S. at 590. If the relevance of physician training comes up at trial, Plaintiffs may move to revisit the issue.

B. Prof. Dr. Med. Uwe Klinge

Plaintiffs disclosed Professor Dr. Med. Uwe Klinge on issues of general causation. Dr. Klinge is a German biomaterial researcher whose former surgical practice focused on hernia repair. The MDL Court stated that "he has implanted and studied the Prolene mesh used in the TVT many

times" and "is the author or co-author of 'over 100' peer-reviewed publications which involve hernia and/or surgical mesh." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). Dr. Klinge's work experience includes ten years as a consultant to Ethicon, from 1994 to 2004, during which time he performed hundreds of studies on the Prolene mesh used by Ethicon in nearly all of its SUI and POP products. Dr. Klinge has studied, tested, and been published numerous times in peer-reviewed literature on the design properties of the Prolene mesh used in Ethicon's TVT meshes.

Defendants seek to exclude Dr. Klinge's opinion that:

> There are alternative design characteristics that would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT. One such safe alternative design would be a mesh product with less material and larger distance between the mesh fibers (Ethicon's Ultrapro mesh has 3-5mm between the fibers and has a weight of 25g/m2).

(ECF No. 90-1 at 37, Expert Report of Uwe Klinge.)

Defendants do not challenge Dr. Klinge's qualifications but move to exclude his opinions about alternative designs as unreliable and speculative on the grounds they are unsupported by testing or scientific literature. Defendants contend Dr. Klinge does not "identify even a single clinical study to prove the safety and efficacy of a mid-urethral sling using Ultrapro." (ECF No. 90 at 5-6.) Defendants also contend Dr. Klinge's alternative design opinions contradict his previous testimony.

Another district court commented in facing similar arguments, "Given Dr. Klinge's qualifications and experience, it is arguable that his experience-based opinions would be reliable in the absence of support from peer-reviewed studies." Williams v. Ethicon, Inc., No. 5:20-CV-234 (MTT), 2021 WL 1087808, at *5 (M.D. Ga. Mar. 22, 2021)). That said, contrary to Defendants' assertion, Dr. Klinge testified in a 2015 deposition that the Ultrapro mesh design is superior to the Prolene mesh design, and cited a supporting scientific study:

> The Ultrapro in its present form, or with these huge pores with this material reduction, has of course advantages in comparison to the Prolene material in regard to the tissue response. There has been a Turkish study clearly showing that it can be used as an alternative . . . for treatment of stress urinary incontinence.

(ECF No. 90-4 at 25, Klinge 10/5/2015 Dep. 91:7-17). The referenced study, which is in Dr. Klinge's reliance materials, is Okulu, E., et al., (2013), "Use of three types of synthetic mesh material in sling surgery. A prospective randomized clinical trial evaluating effectiveness and complications," Scandinavian J. of Urology, 2013, 47:217-224 (the "Okulu study"). The Okulu study concluded that "Ultrapro mesh can be used in sling surgery due to its higher success rates, and its lower vaginal and urethral extrusion and de novo urgency rates, which have also been shown in clinical studies." Further, Dr. Klinge explains in a comprehensive discussion in his expert report the basis for his opinion that lighter weight, large-pore mesh is safer than Prolene, supported by citation to numerous peer-reviewed published articles, his research and experience, Ethicon documents, and deposition testimony. (Klinge Report, ECF No. 90-1 at 9-29.)

Ethicon replies that the Okulu study cannot provide a reliable basis for Dr. Klinge's opinion because it analyzed Ultrapro and Prolene meshes when used in a different urinary stress incontinence surgery known as a "double-forced sling." The study is relevant, however, to show that Ultrapro mesh results in fewer complications than Prolene mesh in some SUI procedures. "For example, the Okulu study concluded Ultrapro mesh incorporated with tissue more successfully because of its 'macropores,' which is the point of Dr. Klinge's opinion." Williams, 2021 WL 1087808, at *5. The Okulu study supports Dr. Klinge's opinions that Ultrapro is a safer alternative. A number of courts have concluded that Dr. Klinge's opinion that the Ultrapro mesh is safer than the mesh used in the TVT products because of its characteristics is not speculative. See Williams, 2021 WL 1087808, at *4-5; Geery, 2021 WL 2580144, at *5; Laderbush, 2020 WL 3001958, at *2.

To the extent Dr. Klinge has testified he has some reservations about the use of Ultrapro, or that he would not want polypropylene mesh including Ultrapro in his own body, these are matters for cross-examination and not a basis for exclusion under Rule 702. See Williams, 2021 WL 1087808, at *5 (citing Winebarger, 2015 WL 1887222, at *10 (alleged "[c]ontradictions in testimony should be address on cross-examination"; citing Daubert, 509 U.S. at 596) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.")).

Finally, Defendants' citation to the decision in Willet v. Johnson & Johnson, 465 F.Supp.3d 895, 908-10 (S.D. Iowa 2020), does not warrant a different result. Willet is not binding on this Court and is distinguishable because it applied Iowa law, which has adopted the "reasonable alternative design/risk utility" test of the Restatement (Third) of Torts: Product Liability, §§ 1 and 2 (1998).[6] Id. at 904. The Missouri Supreme Court has "expressly disavowed" and declined to adopt the Restatement (Third) risk-utility test. Rodriguez v. Suzuki Motor Corp., 996 S.W.2d 47, 65 (Mo. 1999) (en banc) (citing Nesselrode, 707 S.W.2d at 377-78). Willet is therefore unpersuasive. In addition, Willet concerned the testimony of a different expert, Dr. Zipper, who offered case-specific rather than general causation opinions. As the Eighth Circuit has emphasized, the standard for admissibility of general causation opinions in particular is "lower than the merits standard of correctness." Amador, 2021 3612753, at *13 (citing Kuhn, 686 F.3d at 625).

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[6]"The Third Products Restatement section 2, as adopted [by the Iowa Supreme Court], requires plaintiffs in design defect cases to demonstrate the existence of a reasonable alternative design." Scott v. Dutton-Lainson Co., 774 N.W.2d 501, 506 (Iowa 2009) (citing Restatement (Third), § 2(b)). The plaintiff must also show that the alternative design could have been practically adopted at the time of sale or distribution and that the omission of the alternative design caused the product to be not reasonably safe. Nationwide Agribusiness Ins. Co. v. SMA Elevator Constr. Inc., 816 F.Supp.2d 631, 658 n.7 (N.D. Iowa 2011) (citing, among other sources, Restatement (Third), § 2(b)). See also Newman v. Ford Motor Co., 975 S.W.2d 147, 152-53 (Mo. 1998) (en banc) (describing the Restatement (Third)'s risk-utility test).

In sum, Dr. Klinge's opinions regarding safer alternative designs are sufficiently reliable for purposes of Rule 702. Defendants' motion will be denied.

C. Dr. Paul J. Michaels, M.D.

Dr. Paul J. Michaels, M.D. was disclosed by Plaintiffs on issues of both general and specific causation. His general causation opinions are at issue here. Dr. Michaels is a pathologist who is board certified in anatomic pathology, clinical pathology, and cytopathology. "A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information." Eghnayem v. Bos. Sci. Corp., 57 F.Supp.3d 658, 712 (S.D. W. Va. 2014). Defendants do not challenge Dr. Michaels' qualifications or the relevance of his testimony but move to exclude his general causation opinions on alternative designs to Ethicon's mesh products as unreliable.

In his general expert report, Dr. Michaels discusses alternative mesh designs that he contends do not present the same risks as the polypropylene in the TVT-S product. Dr. Michaels states that mesh made of absorbable material and mesh with larger pore sizes (size between filaments) have better incorporation into surrounding tissue than mesh with non-absorbable material and smaller pore sizes. (ECF No. 92-1 at 3-4.) He cites to numerous scientific studies to support his opinions. (Id.)

Defendants argue Dr. Michaels' opinion is unreliable because his discussion of alternative designs is unsupported by testing or scientific literature demonstrating that his proposed alternatives are safer than or at least as effective as the TVT-S. "Dr. Michaels need not conduct the testing when he bases his opinion on his experience and the medical literature." Geery, 2021 WL 2580144, at *4 (citing Katsiafas v. C.R. Bard, Inc., No. 2:19-cv-822-FtM-60MRM, 2020 WL 1808895, at *3 (M.D. Fla. Apr. 9, 2020)). Defendants assert that Dr. Michaels does not identify a single clinical study to prove the safety and efficacy of a device used to treat SUI composed of

alternate materials. "But Dr. Michaels describes, with citations in support, how a pathological response to synthetic grafts depends on the properties of the graft, such as mesh absorbability, pore size, and weight. [(ECF No. 100-1 at 3-4.)]" Geery, 2021 WL 2580144, at *5 (citing Williams, 2021 WL 1087808, at *7). And Dr. Michaels further states that, based on cited studies, lightweight large pore meshes "have a favorable host response" with "better tissue integration with less inflammation and scar fibrosis[.]" (ECF No. 100-1 at 4.)

Defendants' reliance on Willet v. Johnson & Johnson, 465 F.Supp.3d 895, does not warrant exclusion for the reasons discussed above. In addition, the standard for admissibility of general causation opinions in particular is "lower than the merits standard of correctness." Amador, 2021 3612753, at *13 (citing Kuhn, 686 F.3d at 625). Defendants' motion will be denied.

D. Dr. Ralph Zipper, M.D.

Dr. Zipper was disclosed by Plaintiffs as a general causation expert. Dr. Zipper is a pelvic surgeon and urogynecologist. Defendants move to exclude Dr. Zipper's opinions about (1) what the TVT-S Instructions for Use ("IFU") should or should not include, and (2) alternative surgical procedures and alternative designs.

1. Opinions on the TVT-S IFU

Plaintiffs intend to offer Dr. Zipper's testimony that the TVT-S's IFU was defective and failed to provide adequate warnings and information to treating surgeons. Defendants move to exclude this testimony, stating that the MDL Court excluded Dr. Zipper's opinions on the adequacy of the IFUs of mesh products Prosima and Prolift in Wave 1 on the basis that he lacked the necessary qualifications to opine on product warnings.[7] Specifically, the MDL Court ruled

[7] Dr. Zipper offered general opinions concerning the TVT-S product for the first time in Wave 6 of the MDL. Defendants moved to exclude the new opinions but the MDL Court never adjudicated those challenges.

that "a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, [but] must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016). The MDL Court concluded, "Dr. Zipper does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." Id. at *3.

Defendants assert that many of Dr. Zipper's opinions on the TVT-S IFU duplicate his excluded opinions, and his curriculum vitae and prior deposition testimony reveal insufficient experience in preparing a medical device IFU and no training concerning FDA regulations related to developing warnings or labeling. Defendants contend the Court should exclude Dr. Zipper's opinions as to the TVT-S IFU in accordance with the MDL Court's Wave 1 ruling.

Plaintiffs respond that the MDL Court itself indicated it would revisit issues if there was a change in circumstances. Plaintiffs contend that since the time of the MDL Court's ruling, Dr. Zipper has "gained meaningful experience in drafting IFUs for medical devices, including drafting the language regarding safety issues, risks, warnings, efficacy analysis and validation" in his role as an "industry executive of two medical device companies." (ECF No. 102 at 8.) In support, Plaintiffs cite to Dr. Zipper's expert report dated July 27, 2017 (ECF No. 102-2) and deposition testimony of October 27, 2017 (ECF No. 102-5 at 94:22-96:1).

The Court has reviewed the cited portions of Dr. Zipper's expert report and deposition testimony, which have not been supplemented since 2017, and finds they do not provide a basis for departing from the MDL Court's ruling. Defendants' motion to exclude Dr. Zipper's IFU opinions will be granted.

2. Opinions on alternative surgical procedures and alternative designs

Defendants move to exclude Dr. Zipper's opinion that "natural tissue, native tissue surgery [such as MMK and Burch Procedure] is more likely than not safer and better in the long run, if not in the short run" for treatment of SUI than the TVT-S. Defendants assert this opinion concerns alternative treatments for SUI, not alternative designs to the TVT-S, and as such is irrelevant and inadmissible to establish a safer design of the TVT-S product. The Court will deny this motion for the reasons discussed above with respect to Dr. Rosenzweig's similar testimony.

Defendants also move to exclude Dr. Zipper's opinion that the lightweight, large pore Ultrapro mesh was a "safer alternative" to Prolene mesh, on the grounds that no Ultrapro product was available on the market to treat SUI and there is no safety data to prove the opinion. Defendants contend that Dr. Zipper's testimony "does not link his conclusions to the analysis, if any, that he performed to determine that an SUI device made of Ultrapro is indeed safer or feasible," and state that he testified a TVT-S made of Ultrapro would still be defective. (ECF 94 at 10.)

While the MDL Court did not address this issue as to Dr. Zipper, it found Dr. Rosenzweig's opinion that Ultrapro was a safer alternative design for mesh products to be reliable. In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2327, 2020 WL 1061091, at *4 (S.D. W. Va. Feb. 13, 2020). Dr. Zipper similarly has extensive experience with surgical mesh, and relies upon similar methodology in reaching his opinion, including assessment of peer-reviewed scientific and medical literature, internal company documents, and deposition testimony of Ethicon's employees. As discussed above with respect to Dr. Klinge, Dr. Zipper's opinion that lighter weight, large-pore mesh is safer than Prolene is supported by citation to numerous peer-reviewed published articles in the scientific and medical literature; by Ethicon's own analysis of contraction and tissue integration of Prolene, Prolene Soft, and Ultrapro meshes which found that Ultrapro contracted the

least; and by the Okulu study listed in Dr. Zipper's reliance materials which shows that Ultrapro mesh results in fewer complications than Prolene mesh in some SUI procedures.

Dr. Zipper's statement that the TVT-S would still be a defective product if made with Ultrapro is not a basis to exclude the opinion. He testified that use of Ultrapro rather than Prolene would have a substantial chance of reducing complications associated with fibrosis, contraction, and pain. (ECF No. 94-4 at 22-23, Zipper Dep. 10/27/2017, 81:15-82:1.) In rejecting a comparable argument, the MDL Court stated, "[W]hether an alternative device has few complications is surely related to whether the alternative is safer." In re Ethicon, 2020 WL 1061091, at *4. This is a matter for cross-examination. See Amador, 2021 WL 3612753, at *5 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.") (quoting Daubert, 509 U.S. at 596).

Finally, Defendants' citation to the decision in Willet, 465 F.Supp.3d at 908-10, does not warrant a different result. As previously stated, Willet is not binding on this Court and is distinguishable and unpersuasive because it applied Iowa law—which differs significantly from Missouri law as to a plaintiff's prima facie case—to Dr. Zipper's case-specific opinions, rather than the general causation opinions at issue here. As the Eighth Circuit has emphasized, the standard for admissibility of general causation opinions in particular is "lower than the merits standard of correctness." Amador, 2021 WL 3612753, at *13 (citing Kuhn, 686 F.3d at 625).

V. Conclusion

For the foregoing reasons, Plaintiffs' Motions to exclude or limit the opinions and testimony of Defendants' general causation experts are denied, and Defendants Ethicon, Inc. and Johnson & Johnson's Motions to exclude or limit the opinions and testimony of Plaintiffs' general causation experts are granted in part and denied in part, as set forth above.

Accordingly,

IT IS HEREBY ORDERED that Plaintiffs' Daubert Motion to Exclude or Limit the Opinions and Testimony of Brian J. Flynn, M.D., is **DENIED**. (ECF No. 84)

IT IS FURTHER ORDERED that Plaintiffs' Daubert Motion to Exclude or Limit the Opinions and Testimony of Salil Khandwala, M.D., is **DENIED**. (ECF No. 85)

IT IS FURTHER ORDERED that Plaintiffs' Daubert Motion to Exclude or Limit the Opinions and Testimony of Christopher Ramsey, M.D., is **DENIED**. (ECF No. 86)

IT IS FURTHER ORDERED that Defendants Ethicon, Inc. and Johnson & Johnson's Renewed Motion to Limit the Opinions of Bruce Rosenzweig, M.D. is **DENIED without prejudice** as to opinions regarding adverse reporting events; is **GRANTED** as to opinions regarding physician training, although this may be revisited at trial; and is otherwise **DENIED**. (ECF No. 87)

IT IS FURTHER ORDERED that Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Limit Testimony of Prof. Dr. Med. Uwe Klinge is **DENIED**. (ECF No. 89)

IT IS FURTHER ORDERED that Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Exclude the Opinions and Testimony of Paul J. Michaels, M.D., is **DENIED**. (ECF No. 91)

IT IS FURTHER ORDERED that Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Exclude General-Causation Testimony of Ralph Zipper, M.D. is **GRANTED** as to opinions about the TVT Secur Instructions For Use, and is otherwise **DENIED**. (ECF No. 93).

Ronnie L. White

RONNIE L. WHITE
UNITED STATES DISTRICT JUDGE

Dated this 1st day of September, 2021.